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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,194	10/28/2003	Denis Francois Hochstrasser	A36054-PCT-USA-A 072874.0	4418
21003	7590	12/20/2004	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/695,194

Applicant(s)

HOCHSTRASSER ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on preliminary amendment.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Preliminary Amendment, received 30 July 2004, is acknowledged.
2. Claims 1-47 are pending.

### **Election/Restrictions**

3. Claims 20, 21, and 22 are drawn to multiple inventions, i.e., a method of diagnosis and a method of therapy. Therefore, the claims are placed into multiple invention groups. Election of one of the invention groups means that claims 20, 21, and 22 will be drawn solely to that invention.
4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-19, 21, 22, and 29-46, drawn to method and kit for diagnosis of TSE by detecting polypeptide, classified in class 436, subclass 501.
  - II. Claim 20, drawn to method for diagnosis of TSE by detecting antibody, classified in class 435, subclass 7.1.
  - III. Claim 20, drawn to therapy using polypeptide, classified in class 424, subclass 184.1.
  - IV. Claims 21 and 22, drawn to therapy using antibody, classified in class 424, subclass 130.1.
  - V. Claims 23-28, drawn to device using antibody, classified in class 436, subclass 524.
  - VI. Claim 47, drawn to normal bovine animals, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II are drawn to two distinct methods. Invention I is a method for detecting polypeptides while Invention II is a method for detecting antibodies.

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Invention I and III are drawn to two distinct methods. Invention I is a method for diagnosis of disease while Invention III is a method of therapy for infected hosts.

Invention I and IV are drawn to two distinct methods using different reagents. Invention I is a method for diagnosis of disease by detecting polypeptides while Invention IV is a method of therapy for infected hosts utilizing antibodies.

Invention I and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process of Invention I can be performed with a materially different apparatus, i.e., mass spectrometry.

Invention I and VI are drawn to patentably distinct inventions. Invention I is a method for diagnosis of disease while Invention VI is a normal bovine animal.

Invention II and III are drawn to different methods utilizing different reagents and having different endresults.

Invention II and IV are drawn to different methods utilizing different reagents and having different endresults.

Invention II and V are drawn to different methods and device. Invention II is a method for diagnosis by detecting antibody while Invention V is a device with bound antibody for detecting polypeptides.

Invention II and VI are drawn to patentably distinct inventions. Invention II is a method for diagnosis and Invention VI is a normal bovine animal.

Invention III and IV are drawn to different methods, utilizing different reagents and different methods steps.

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Invention III and V are drawn to structurally and functionally distinct inventions. Invention III is drawn to polypeptides while Invention V V is a device with bound antibody.

Invention III and VI are drawn to patentably distinct inventions. Invention II is a method of therapy for infected animals and Invention VI is a normal bovine animal.

Invention IV and V are drawn to different methods, utilizing different reagents and different methods steps. Invention IV is a method of therapy using antibody while Invention V is a device for detection of polypeptides.

Invention IV and VI are drawn to patentably distinct inventions. Invention IV is a method of therapy for infected animals and Invention VI is a normal bovine animal.

Invention V and VI are drawn to structurally and functionally distinct products. Invention V is is a device for detection of polypeptides and Invention VI is a normal bovine animal.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

December 15, 2004